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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,596	02/15/2002	Alan D. Snow	017170-0010-999	2850
20583	7590	10/28/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			JIANG, SHAOJIA A	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/077,596

Applicant(s)

SNOW ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-41, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-41 and 55-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to Applicant's amendment and response filed on August 23, 2005 wherein claim 28 has been amended. Claims 1-27 and 42-54 are cancelled previously.

Currently, claims 28-41 and 55-56 are pending in this application.

Claims 28-41 and 55-56 are currently under examination on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznicki et al. (5,681,569 of record).

Kuznicki et al. discloses a composition **comprising** green tea solids extracted from tea material, i.e., 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate (see particularly col.3 lines 20-21 and 26-28), and a pharmaceutical carrier (i.e., water). See also abstract, col.2, lines 12-14; Example I, II, and III at col.10, and claims 1 and 5-6. Thus, the green tea composition of Kuznicki et al. **inherently** comprises **proanthocyanidins** **oligomers** having the formula I

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and II herein and/or **procyanidins** such as the dimers and trimers of catechin and epicatechin herein.

The inherency of the green tea compositions containing proanthocyanidins and/or procyanidins is supported by the references by Hashimoto et al. (see "FC" in PTO-1449 submitted April 30, 2004). Hashimoto et al. teach that proanthocyanidins are isolated from oolong tea (a well known green tea), and/or the flesh leaves of green teas therein, wherein proanthocyanidins can be degraded to catechin and epicatechins by hydrolysis. Most importantly the compounds identified by Hashimoto et al. in the green tea compositions are the instant compounds having the formula I or II (see Chart 2, the first two compounds on the top of page 3257). Morimoto et al. also teach that proanthocyanidins or procyanidins wherein proanthocyanidins can be degraded to catechins and epicatechins.

Kuznicki et al. also discloses the composition therein is therapeutically useful in improving cognitive performance (see col.3 line 33 in particular). The therapeutic effective amount of a catechin or mixture of catechins, within the instant claim (10-100mg/kg of body weight of the subject), is disclosed in the Example I and III (see col. 10 lines 1-41) as shown in the calculation below:

Example III discloses that a person can consume 835 cc (835 ml) of a beverage prepared according to Example I (see col.10 lines 40-41).

Since the water in the composition in Example I is 94.45%, the composition is aqueous solution. The density of water = 1 g/ml, thus the total amount of the composition in Example I is 835 g.

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According to Example I, the effective amount of catechins (or flavanols)

$$= 835\text{g} \times 0.097\% \text{ (see col.10 line 15 in particular)} = 0.8099 \text{ g} = 809.9 \text{ mg}$$

OR in different calculation, according to Example I (see particularly at col.10 lines 6 and 13-14)

the effective amount of catechins

$$= 835\text{g} \times 0.35/100 \times 29/100 = 0.8475 \text{ g} = 847.5 \text{ mg.}$$

Since a standard person weight is 70 kg, the range of effective amounts of catechins is  $10 \text{ mg/kg} \times 70 \text{ kg} = \underline{700 \text{ mg}}$  to  $1000 \text{ mg/kg} \times 70 \text{ kg} = 70,000 \text{ mg}$ .

Thus, the effective amount of catechins as exemplified in Example I in the composition of Kuznicki et al., 809.9 mg or 847.5 mg, is within the instant claimed range.

Kuznicki et al. also discloses that catechins therein are extracted from green teas or other plants, and isolated from green tea by methods well known to those in the art (see particularly at col.4 lines 6-14). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, which is an inherent property of the composition of Kuznicki et al. Kuznicki et al. also discloses that catechins can be prepared by synthetic chemical method or commercially available (see col.4 lines 14-17).

Note that the limitation "wherein proanthocyanidins is at least 70% pure" is not considered to limit the composition claimed herein, given the transitional phrases "**comprising**" is employed in the instant claimed composition. Applicant is requested to

note that the transitional term “comprising” is **inclusive or open-ended and does not exclude additional, unrecited elements or method steps**. Thus, the composition does not excluded any other ingredients. Moreover, the specification is not seen to clearly define as to “wherein proanthocyanidins is at least 70% pure”, whether proanthocyanidins was insolated from the green tea or plant extract in at least 70% pure. However, the instant claims are directed to a pharmaceutical composition comprising proanthocyanidins, **not** proanthocyanidins insolated from the green tea or plant extract in at least 70% pure.

Thus, Kuznicki et al. anticipates claims 28-41 and 55-56.

### ***Response to Argument***

Applicant's arguments filed August 23, 2005 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art. These remarks are believed to be adequately addressed by the rejection presented above.

Again, note that the transitional phrases “**comprising**” is employed in the instant claimed composition, i.e., the independent claim 28 reads “A pharmaceutical composition comprising a therapeutically effective amount of a proanthocyanidin, selected from..). Applicant is requested to note that the transitional term “comprising” is **inclusive or open-ended and does not exclude additional, unrecited elements or method steps**. See MPEP 2111.03.

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Thus, the instant claimed composition read on the composition of Kuznicki et al. comprising green tea solids extracted from tea material, i.e., 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate, and also proanthocyanidins oligomers having the formula I and II herein, because proanthocyanidins oligomers having the formula I and II herein are also extracted from green teas. Although the structural features of proanthocyanidins oligomers having the formula I and II herein have not been disclosed or identified by Kuznicki et al., proanthocyanidins oligomers having the formula I and II, are inherently **present** in the composition of Kuznicki et al. extracted from green teas. Note that the instant claimed composition is not drawn to a composition consisting of proanthocyanidins oligomers having the formula I and II.

Applicant asserts that proanthocyanidins oligomers having formula I and II are not present in the extract from green teas. Contrary to Applicant's assertion, proanthocyanidins oligomers, are polymeric or oligomeric compounds composed of epicatechin and catechin residues. Disclosed compounds include dimers of epicatechin and catechin residues, and trimers of epicatechin, as admitted by Applicant. Epicatechin and catechin, and the dimmers and oligomers of epicatechin and catechin, and epicatechin and catechin residues. also well known as flavanoids, are known to be present in green teas and obtained from the extraction of green teas.

Further, the inherency of the green tea compositions containing proanthocyanidins and/or procyanidins is supported by the references by Hashimoto et

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al. (see "FC" in PTO-1449 submitted April 30, 2004). Hashimoto et al. teach that proanthocyanidins are isolated from oolong tea (a well known green tea), and/or the flesh leaves of green teas therein, wherein proanthocyanidins can be degraded to catechin and epicatechins by hydrolysis. Most importantly the compounds identified by Hashimoto et al. in the green tea compositions are the instant compounds having the formula I or II (see Chart 2, the first two compounds on the top of page 3257). Morimoto et al. also teach that proanthocyanidins or procyanidins wherein proanthocyanidins can be degraded to catechins and epicatechins.

Note that arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., In re Huang, 100 F.3d 135,139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

**The burden is shifted to Applicant to show that the prior art product does not inherently possess proanthocyanidins and/or procyanidins as instantly claimed product.**

Thus, Kuznicki et al. anticipates claims 28-41 and 55-56.

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 of record.

JP 10245342 discloses a pharmaceutical composition for diminishing the toxicity in nerve cells caused by  $\beta$ -amyloid protein comprising a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate prescribed in effective



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amounts (doses) of diminishing the toxicity of  $\beta$ -amyloid protein (see particularly page 1, the 2<sup>nd</sup> paragraph; claims 1-3 at page 1; page 2 [0001], [0002]), and a pharmaceutical carrier (i.e., water). See also page 7 [0028]; page 8 [0029]. Thus, the green tea composition in JP 10245342 inherently comprises proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin herein since catechins are known to encompass these compounds which are known to be isolated from green tea, as discussed above based on the references by Hashimoto et al., and Morimoto et al.

JP 10245342 also discloses that catechins therein are extracted from teas or other plants, and isolated and purified by HPLC (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, JP 10245342 anticipates claims 28, 31-41 and 55-56.

Applicant's arguments filed August 23, 2005 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the same rationale discussed in the rejection anticipated by Kuznicki et al.

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. of record in PTO-1449 submitted April 30, 2004.

Hashimoto et al. discloses a composition comprising a catechin or two or more of catechins such as epigallocatechin and dimers and proanthocyanidins (having the formula I and II herein) and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carrier (i.e., water). See abstract. Thus, the oolong tea composition in Hashimoto et al. comprises the instant compounds herein since these compounds are known to be isolated from oolong tea. Most importantly the compounds identified by Hashimoto et al. in the green tea compositions are the instant compounds having the formula I or II (see Chart 2, the first two compounds on the top of page 3257).

Hashimoto et al. also discloses that proanthocyanidins are extracted from teas or other plants, and isolated (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, Hashimoto et al. anticipates claims 28, 31-41 and 55-56.

Applicant's arguments filed August 23, 2005 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art. These remarks are believed to be adequately addressed by the rejection presented above.

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Morimoto et al.(PTO-892).

Morimoto et al. discloses a composition comprising a catechin or two or more of catechins such as epigallocatechin and dimers and procyanidins (having the formula I and II herein) such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carrier (i.e., water). See abstract, page 908-909. Most importantly the compounds identified by Morimoto et al. are the instant compounds having the formula I or II (see page 909, Compound 3 and page 908).

Thus, Morimoto et al. anticipates claims 28, 31-41 and 55-56.

Applicant's arguments filed August 23, 2005 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art. These remarks are believed to be adequately addressed by the rejection presented above.

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatano et al. for reasons of record stated in the Office Action dated September 30, 2003.

Hatano et al. discloses a composition for anti-HIV comprising or inherently comprising a catechin or two or more of catechins such as epigallocatechin and dimers or proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts, and a

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pharmaceutical carrier (i.e., water). See abstract. Thus, the composition in Hatano et al. inherently comprises the instant compounds herein since these compounds are known to be isolated from Camellia japonica plants. See abstract.

Hatano et al. also discloses that catechins therein are extracted from plants, and isolated (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

Thus, Hatano et al. anticipates claims 28, 31-41 and 55-56.

Applicant's arguments filed August 23, 2005 with respect to this rejection made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art. These remarks are believed to be adequately addressed by the rejection presented above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
S. Anna Jiang, Ph.D.  
Primary Examiner  
Art Unit 1617  
October 19, 2005